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PRIMARY PLERIXAFOR MOBILIZATION IN AUTOLOGOUS HEMATOPOIETIC CELL TRANSPLANT CANDIDATES AT HIGH RISK FOR MOBILIZATION FAILURE

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Plerixafor has recently become commercially available for use as a mobilizing agent in patients undergoing CD34+ hematopoietic cell collection in preparation for autologous transplantation. Practice guidelines were developed to optimize the use of plerixafor at our institution. Within those guidelines, we defined patients at high risk for mobilization failure as those who met the following criteria: 1) Received 3 lines of prior chemotherapy; 2) Received 2 lines of prior chemotherapy plus a radioimmunoconjugate 3) Received 2 lines of prior chemotherapy plus radiation therapy to extensive fields; 4) Received 4 or more cycles of hyper-CVAD or more than 4 cycles of lenalidomide; 5) Hypocellular marrow (<25% cellularity); 6) Platelet count <100,000/μL

We report here preliminary data on 19 consecutive high-risk patients who have received plerixafor as primary mobilization therapy. The median age of the patients was 60 (range 33-71) years. Diagnoses include multiple myeloma (12), non-Hodgkin's lymphoma (6) and Hodgkin's disease (1). Patients received a median of 2 (range 1-5) lines of prior chemotherapy and 6 patients also received prior radiation therapy. All patients received 4 doses of G-CSF (10 mcg/kg/d) and on the evening of the forth dose, they also received plerixafor 0.24 mg/kg except for 3 patients who were dosed at 0.16 mg/kg due to reduced creatinine clearance. Apheresis was started the morning after the first dose of plerixafor. G-CSF, plerixafor, and apheresis were continued until at least 2×10^6 CD34+ cells/kg were collected. The median number (range) of G-CSF doses, plerixafor doses and aphereses were 4 (4-7), 1 (1-3), and 1 (1-3), respectively. The number of patients collecting at least 2×10^6 CD34+ cells (cumulative) on 1, 2, and 3 aphereses were 15 (79%), 17 (89%), and 19 (100%). The median (range) of the total number of CD34+ cells/kg collected for all patients was 4.99 (2.07-23.65)x 10^6. All patients have been transplanted. Eighteen patients are evaluable for neutrophil recovery; median time to absolute neutrophil count > 500/μL was 12 (range 10-12) days. Fourteen patients have recovered platelet counts > 20,000/μL (without transfusion for 7 days) at median of 18 days (range 14-42) post-transplant. We conclude that plerixafor is beneficial in patients who are at high risk for mobilization failure with 100% of patients mobilizing adequate CD34+ cells counts in 3 aphereses or less.

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AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANTATION WITH INDUCTION OF AUTOLOGOUS GRAFT-VERSUS-HOST DISEASE IN ACUTE MYELOID LEUKEMIA – LONG-TERM F/U DATA

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We previously published data that suggested that induction of an autologous graft-versus-host disease (GVHD) has an anti-leukemic effect, consequently increasing the survival rate of patients who undergo autologous peripheral blood stem cell transplantation (PBSCT). Here we report the long term follow up data regarding the overall survival (OS) and disease free survival (DFS). In total, 22 acute myeloid leukemia patients with favorable and intermediate cytogenetic risk, in their first complete remission, were administered cyclosporine c.i.v. from day 0 to day +28 at a dose of 3.0 mg/kg per day and interferon- γ (IFN- γ) at 0.025 mg//m^2 s.c. every other day from day +14 to day +42 following autologous PBSCT. Natural-killer (NK) – cell activity assays and skin biopsies were performed. Engraftment was successful in all patients at a median of 13 days without any significant additional toxicity. Histologically confirmed that cutaneous GVHD had developed in 12 patients, and NK-cell activity was significantly augmented after the autologous PBSCT in those patients (P = 0.03). After a median follow-up duration of 117.6 months (range, 87.3-152.8), the 3-year DFS and OS rates were 68.2% and 72.7%, respectively, and the 5-year DFS and OS rates were 63.6% and 73%, respectively. They were without significant correlation with GVHD status or augmentation of NK-cell activity. The median OS was unreached yet.

This data suggests that the administration of cyclosporine and IFN-γ following autologous PBSCT improves OS and DFS, which may be attributable to the antileukemic effect, although no difference in survival rates could be demonstrated between cutaneous GVHD-positive and -negative groups.

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VALIDATION OF A DECISION-MAKING ALGORITHM TO GUIDE THE USE OF PLERIXAFOR FOR AUTOLOGOUS HEMATOPOIETIC STEM CELL MOBILIZATION

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Background: Plerixafor, an inhibitor of CXCR-4/SDF-1 binding, is approved for mobilization of peripheral blood hematopoietic stem cells (PBHSC) prior to autologous hematopoietic stem cells transplantation (AHSCT) for non-Hodgkin lymphomas and multiple myeloma (MM). We developed a cost-saving decision making algorithm that utilizes the CD34+ count in the peripheral blood on the 4th day of G-CSF administration (PB-CD34+) and the target CD34+ count for the specific patient (T-CD34+) to decide between starting collection on day 4 and continuing G-CSF administration only (G approach) or adding Plerixafor the night before each apheresis session and starting apheresis on day 5 (G + P approach). The algorithm was based on actual mobilization data and analysis of mobilization charges aiming at finding the approach likely to have the lowest charge for each circumstance. The development of this algorithm has been previously presented (ASH 2009, abstract 3216)

Methods: We reviewed mobilization and collection data on 28 patients who have completed mobilization on the MUSC mobilization algorithm. Additionally, we reviewed engraftment data for the 19 patients who have undergone a first autologous transplantation.

Results: Twenty eight patients have been included in the validation cohort. Patient characteristics are displayed in table 1. Nine patients (33%) completed collections with the G approach and 19 (68%) with the G + P approach. There were no collection failures. Twenty-six

Table 1. Characteristics of the patients included in the validation cohort

Characteristic	Number of patients	Percentage
Diagnosis		
Multiple Myeloma	23	82
Lymphoma	5	18
Age		
≤60	17	61
>60	11	39
Gender		
Male	10	36
Female	18	64
Prior radiation	10	36
Prior lines of therapy- Lymphomas		
≤2	5	100
>2	0	0
Prior lines of therapy- Myeloma		
≤1	10	43
>1	13	57
Prior lenalidomide	14	61
Target CD34+/kg for mobilization		
3x10e6	13	46
6x10e6	15	54